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NOTICE OF ALLOWANCE AND FEE(S) DUE

27317 7590 09/21/2009

Fleit Gibbons Gutman Bongini & Bianco PL
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER

AZARIAN, SEYED H

ART UNIT

PAPER NUMBER

2624

DATE MAILED: 09/21/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,887

08/06/2008

Hadassa Degani

7040-N06-075US

5752

TITLE OF INVENTION: THREE TIME POINT LUNG CANCER DETECTION, DIAGNOSIS AND ASSESSMENT OF PROGNOSIS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	12/21/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

27317 7590 09/21/2009

Fleit Gibbons Gutman Bongini & Bianco PL
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,887 08/06/2008 Hadassa Degani 7040-N06-075US 5752

TITLE OF INVENTION: THREE TIME POINT LUNG CANCER DETECTION, DIAGNOSIS AND ASSESSMENT OF PROGNOSIS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional YES \$755 \$300 \$0 \$1055 12/21/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
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AZARIAN, SEYED H 2624 382-131000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,887	08/06/2008	Hadassa Degani	7040-N06-075US	5752
27317	7590	09/21/2009	EXAMINER	
Fleit Gibbons Gutman Bongini & Bianco PL 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180			AZARIAN, SEYED H	
			ART UNIT	PAPER NUMBER
			2624	
DATE MAILED: 09/21/2009				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/593,887	DEGANI ET AL.	
	Examiner	Art Unit	
	Seyed Azarian	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/6/2008, also telephone interview and fax inquiry filed on September 9 and 14.
2. ☒ The allowed claim(s) is/are 1-36.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>11/21/2008</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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/Seyed Azarian/
Primary Examiner, Art Unit 2624

Drawings

1. The drawing filed on 9/21/2006 is accepted by the Examiner.

Response to Amendment

1. Based on applicant's amendment, also telephone interview and fax inquiry filed on September 9 and 14, 2009, with respect to amended claims 1 and 19, have been fully considered and are persuasive, upon further consideration, the rejection of prior art of record for claims 1-36, are hereby withdrawn.

The claims 1-36 are allowed.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicants Attorney (Mr. Martin Fleit, Reg No. 16,900), on September 2 and 14, 2009, without traverse.

The amended claims 1 and 19 as follows:

Claim 1. (Currently Amended) A method of providing a malignancy classification for a region of lung tissue, the method comprising:

setting time points T1 and T2 measured from a time point T0 at or near an injection of a contrast agent, T1 representing a wash-in time point for malignant lung tissue at which a first concentration value of the injected contrast agent is substantially equal to or near a peak for injected contrast agent concentration for the malignant lung tissue,

wherein at T2 a second concentration value of the injected contrast agent for the malignant lung tissue is less than or substantially equal to the first concentration value at T1, and a third concentration value of the injected contrast agent for non-malignant lung tissue at T1 is less than or substantially equal to a fourth concentration value of the injected contrast agent concentration for the non-malignant lung tissue at T2;

wherein the setting of the time points T1 and T2 is determined from degree of changes in concentration values in the region of the lung tissue between time points T1 and T2 satisfying a preselected condition based on a maximum intensity predicated on microvascular permeability and extracellular volume of the region of lung tissue;

obtaining a first sample concentration value of the contrast agent for the region of lung tissue at T1 and a second sample concentration value of the contrast agent for the region of lung tissue at T2;

determining a malignancy classification for the region of lung tissue by comparing the obtained sample concentration values with a predetermined malignancy profile; and

outputting a visual representation of the malignancy classification of the region of lung tissue.

Claim 19. (Currently Amended) A computer-readable medium incorporating a program of instructions for providing a malignancy classification for a region of lung tissue, the program of

Art Unit: 2624

instructions comprising:

instructions for setting time points T1 and t2 measured from a time point T0 at or near an injection of a contrast agent, T1 representing a wash-in time point for malignant lung tissue at which a first concentration value of the injected contrast agent is substantially equal to or near a peak for injected contrast agent concentration for the malignant lung tissue,

wherein at T2 a second concentration value of the injected contrast agent for the malignant lung tissue is less than or substantially equal to the first concentration value at T1, and a third concentration value of the injected contrast agent for non-malignant lung tissue at T1 is less than or substantially equal to a fourth concentration value of the injected contrast agent concentration for the non-malignant lung tissue at T2;

wherein the setting of the time points T1 and T2 is determined from degree of changes in concentration values in the region of the lung tissue between time points T1 and T2 satisfying a preselected condition based on a maximum intensity predicated on microvascular permeability and extracellular volume of the region of lung tissue;

instructions for obtaining a first sample concentration value of the contrast agent for the region of lung tissue at T1 and a second concentration value of the contrast agent for the region of lung tissue at T2;

instructions for determining a malignancy classification for the region of lung tissue by comparing the obtained sample concentration values with a predetermined malignancy profile; and

Art Unit: 2624

instructions for outputting a visual representation of the malignancy classification of the region of lung tissue.

REASONS FOR ALLOWANCE

3. The following is an examiner's statement of reasons for allowance.

This invention relates generally, to medical imaging devices generally, and to methods, systems, and programs of instructions for the evaluation of potentially malignant tissue based on computed tomography (CT) or other such imaging devices.

Based on applicant's amendment, with respect to claim 1 representative of claim 19 the closest prior art of record (Klotz 7,203,353), reference directed to a method for image processing proceeding from a computer tomography (CT) image of a lung registered with a contrast agent, we well as a CT apparatus for the implementation of such a method, but does not teach or suggest, among other things, "wherein at T2 a second concentration value of the injected contrast agent for the malignant lung tissue is less than or substantially equal to the first concentration value at T1, and a third concentration value of the injected contrast agent for non-malignant lung tissue at T1 is less than or substantially equal to a fourth concentration value of the injected contrast agent concentration for the non-malignant lung tissue at T2, wherein the setting of the time points T1 and T2 is determined from degree of changes in concentration values in the region of the lung tissue between time points T1 and T2 satisfying a preselected condition based on a maximum intensity predicated on microvascular permeability and extracellular volume of the region of lung tissue; obtaining a first sample concentration value of the contrast agent for the region of lung tissue at T1 and a second sample concentration value of the contrast agent for the region of lung tissue at T2".

These key features in combination with the other features of the claimed invention are neither taught nor suggested by (Klotz) prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Contact Information

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (571) 272-7443. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella, can be reached at (571) 272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.

Status information about the PAIR system, see [http:// pair-direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Seyed Azarian
Patent Examiner
Group Art Unit 2624
September 14, 2009*